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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,943	08/28/2003	Itzhak Bentwich	06087.0300.CPUS07	1942
22930	7590	03/13/2006	EXAMINER	
HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DR, SUITE 200 FALLS CHURCH, VA 22042-2924			MILLER, MARINA I	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/604,943

Applicant(s)

BENTWICH, ITZHAK

Examiner

Marina Miller

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Sequence Rules Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) are present in the specification, *e.g.*, pages 49-50 paragraph [0151] and Fig. 12A, 13A, and 14A, but those sequences are not identified in the Figures or the specification by a sequence identifier (SEQ ID NO:).

Applicants are reminded that when a sequence is presented in a drawing, the sequence must still be identified by the Sequence Listing and the sequence identifier must be used, either in the drawing or in the Brief Description of the Drawings.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this action within which to comply with the sequence rules, 37 CFR 1.821-1.825, said time period to run concurrently with the time period for reply to the Restriction/Election requirement set forth below. Any requirement to the Restriction/Election requirement before the sequence rules have been complied with will be considered nonresponsive. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension

Art Unit: 1631

fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 11-12, and 14, drawn to a gene, a vector, a gene expression system, and a probe, classified in class 536, subclass 23.1.
- II. Claims 9-10, drawn to a method of selectively inhibiting translation, classified in class 435, subclass 455.
- III. Claims 13-14, drawn to a method and a system of selectively detecting expression, classified in class 435, subclass 5.
- IV. Claims 15-17, drawn to an anti-viral substance, classified in class 536, subclass 23.1.
- V. Claims 18-20, drawn to a method for an anti-viral treatment, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to Inventions II and III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a gene or probe of Invention I may be used

in two different methods, *i.e.*, the method of selectively inhibiting translation (Invention II) or the method of selectively detecting expression (Invention III).

Invention I and Invention IV are unrelated. Invention I is directed to a viral gene/probe and Invention IV is directed to an anti-viral substance capable of neutralizing RNA encoded by the gene. Thus, different inventions I and IV have different designs, modes of operation, and effect.

Invention I and Invention V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention I is directed to a viral gene/probe and Invention V is directed to a method wherein RNA encoded by the viral gene is bound by an agent. Thus, different inventions I and V have different designs, modes of operation, and effect.

Invention II, III, and V can be shown to be distinct because they are physically and functionally different, and not required one for the other. The method of Invention II is directed to a method for selectively inhibiting translation, the method of Invention III is directed to selectively detecting expression, and the method of Invention V is directed to a method of anti-viral treatments comprising steps of neutralizing, synthesizing a complementary nucleic acids, and transfecting a host cell. Thus, the Inventions have a different goal and method steps. Additionally, the methods of Inventions II-III, for example, do not require manipulations that are required by the method of Invention V.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation,

Art Unit: 1631

and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention II is directed to a method of selectively inhibiting translation comprising introducing a vector which comprises a novel viral gene encoding RNA capable of binding to a host target gene. Invention IV is directed to an anti-viral substance capable of neutralizing RNA encoded by the novel viral gene. Thus, the Inventions have different designs, modes of operation, and effect.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention III is directed to a method of selectively detecting expression comprising using a probe comprising a novel viral gene encoding RNA capable of binding to a host target gene. Invention IV is directed to an anti-viral substance capable of neutralizing RNA encoded by the novel viral gene. The method of Invention III does not require using an anti-viral substance of Invention IV. Moreover, the anti-viral substance of Invention III and the method of Invention IV are not capable of using together. Thus, the Inventions have different designs, modes of operation, and effect.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention IV is directed to an antiviral substance capable of neutralizing RNA. An antiviral substance capable of neutralizing RNA may comprise, for example, a protein (*e.g.*, RNase, RNA polymerase), DNA, RNA, an antibody, or a chemical (a drug, an intercalator). Invention V is directed to a method for antiviral treatment comprising neutralizing RNA. The method recites neutralizing by using a nucleic acid molecule of a partially inversed-reversed sequence. The antiviral substance of Invention IV is not

required to be a partially inversed-reversed nucleic acid sequence. Therefore, the Inventions have different design, modes of operation, and effects.

Because these Inventions are distinct for the reasons given above, the classification is different, and the non-patent and patent literature search required for each group is not coextensive with that requirement for another group, restriction for examination purposes as indicated is proper.

***Sequence Restriction/Election Requirement Applicable to All Groups.***

In addition, each Group detailed above reads on patentably distinct novel viral gene/sequences. Absent evidence to the contrary, each nucleotide sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Each gene/sequence is patentably distinct because they are unrelated sequences and have different structure and function. For any elected Group which recites a viral gene/sequence, applicants must elect a single disclosed gene/sequence (*See* MPEP § 803.04).

Examination will be restricted to only the elected gene/sequence.

This election of a gene/sequence is not a species election.

***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: elect one disclosed target gene.

Art Unit: 1631

The election of a target gene inhibited by the elected novel viral gene is required for purposes of initial examination. Applicants are reminded that the elected target gene must be a gene that is a target for the elected novel viral gene encoding RNA. *See* MPEP § 809.02(a).

Species B: elect one neutralizing process among complementarily binding RNA and immunological neutralizing recited in claims 15-20.

Species A of different target genes are distinct because they have different structure and function and are not related one to the other.

Species B of neutralizing process are distinct because they are structurally and functionally different and independent. Data generated for one type of neutralizing are expected to be different from the data generated for any other neutralizing process.

Applicant is required under 35 U.S.C. 121 to elect ONE disclosed species from EACH of groups A-B above, where applicable, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the



limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Examiner  
Art Unit 1631

MM

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*2/22/06*